

POVIDINE IODINE - povidine iodine swab
Dynarex Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Povidone Iodine Gel Swabstick

Active Ingredient

Povidone Iodine 10% v/v

Purpose

Antiseptic

Uses:

- First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infections.

Warnings:

- **FOR EXTERNAL USE ONLY**

Do not use:

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

Ask a doctor before use if you have:

- Deep puncture wounds
- Animal bites
- Serious burns

Stop Use:

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

Keep Out Of Reach Of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.

Directions Povidone Iodine Gel Swabstick:

Tear at notch, remove applicator, use only once.

As a first aid antiseptic

- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

Other information:

Sterile

Store at room temperature.

Avoid excessive heat

For use as an

- first aid antiseptic
- pre-operative skin preparation

Inactive Ingredients

Inactive ingredients: citric acid, glycerol, nonoxynol-10, sodium hydroxide, water

Principal Display Panel

PVP_Gel_Swabstick

<p>50 Packets</p> <p>NDC# 67777-301-01</p> <p>Povidone-Iodine Gel Swabsticks Antiseptic Skin Prep Latex Free Sterile unless pouch is opened or damaged</p> 	<p>50 Packets</p> <p>Povidone-Iodine Gel Swabsticks Antiseptic Skin Prep Latex Free Sterile unless pouch is opened or damaged</p> <p>Manufactured for: DYNAREX Corporation Orangeburg, NY 10962 www.dynarex.com</p> 	<p>50 Packets</p> <table border="1"><tr><td>Drug Facts</td><td></td></tr><tr><td>Active Ingredient.....</td><td>Purpose Povidone iodine 10%..... Antiseptic</td></tr><tr><td>Uses</td><td>Antiseptic cleanser to help prevent skin infection in minor cuts, scrapes, and burns</td></tr><tr><td>Warnings</td><td>For External Use Only. Do not use</td></tr><tr><td>Directions</td><td>Use at each • Remove applicator • Use only once</td></tr></table>	Drug Facts		Active Ingredient	Purpose Povidone iodine 10%..... Antiseptic	Uses	Antiseptic cleanser to help prevent skin infection in minor cuts, scrapes, and burns	Warnings	For External Use Only. Do not use	Directions	Use at each • Remove applicator • Use only once
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<p>Reorder No. 1208</p>	<p>Reorder No. 1208</p>	<p>Made in China</p> <p>Reorder No. 1208</p>										

POVIDINE IODINE

povidine iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-10 (UNII: K7O76887AP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-301-01	10 in 1 CASE		
1		50 in 1 BOX		
1		1 in 1 POUCH		
1		.3 mL in 1 POUCH		
2	NDC:67777-301-02	10 in 1 CASE		
2		25 in 1 BOX		
2		3 in 1 POUCH		
2		.9 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/10/2012	

Labeler - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)